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Part II

# Department of Health, Education, and Welfare

## Food and Drug Administration

## Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food

**DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**

**Food and Drug Administration**

**[21 CFR Parts 20 and 110]**

**[Docket No. 78N-0296]**

## Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposal

**SUMMARY:** The Food and Drug Administration is proposing to revise the current good manufacturing practice (CGMP) regulations for the manufacturing, processing, packing, and holding of human foods. this document would establish new, updated, or more detailed CGMP provisions concerning food industry personnel; plants and grounds; sanitary facilities, controls and operations; equipment and utensils; processes and controls; product coding; warehousing and distribution; recordkeeping; and natural or unavoidable defect levels. As revised by this proposal, the CGTMP regulations would be more directly applicable to the problems associated with foods for which specific CGMP regulations have not been promulgated, and thus would better ensure the production of save and sanitary food. The agency is planning to hold public hearings on this proposal in the fall of 1979. A notice giving specific information about these hearings will be published in the **Federal Register** on or about June 15, 1979.

**DATES:** Comments by December 31, 1979; the agency proposes that the final regulation based on this proposal be effective on or before December 5, 1979.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** F. Leo Kauffman, Bureau of Foods (HFF-414), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1164.

**SUPPLEMENTARY INFORMATION:** Passage of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) in 1938 gave the Food and Drug Administration (FDA) for the first time the authority to establish and impose reasonable sanitation standards on the production of foods, drugs, and cosmetics. For foods, these applicable statutory provisions are found in section 402(a) (3) and (4) of the act (21 U.S.C. 342(a) (3) and (4)), which, among other concerns, defines conditions under which a food is deemed to be adulterated. The legislative history of the act explains that these new provisions were added to expand the agency's bases for initiating enforcement proceedings conducted under the Pure Food and Drug Act of 1906 and, more specifically, to provide control mechanisms against insanitary and otherwise contaminated foods (Ref. 1). Furthermore, Congress granted FDA authority in section 704 of the act (21 U.S.C. 374) to inspect factories, warehouses, and other establishments in which foods are manufactured, processed, packed, or held, and to inspect their facilities, equipment, and materials.

Historically, FDA has used its inspection authority to trigger the legal sanctions provided by the act (1) to prevent the introduction or delivery for introduction into interstate commerce of adulterated food or (2) to prevent adulteration of food while it is being held for sale after shipment in interstate commerce. Under section 402(a)(3) of the act, the food is adulterated if it actually consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Moreover, under section 402(a)(4) of the act, food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. In sum, then, food need not be shown to contain filth or other contaminants to be adulterated; a showing that the food is prepared, packed, or held under conditions whereby it may become so is legally sufficient to prove adulteration.

On the basis of evidence gathered during inspections, FDA then uses its legal authority to go to court to seize the adulterated food, to seek to enjoin its shipment or sale, or to have the persons adulterating the food criminally prosecuted. The number of inspections and court actions instituted by FDA has varied over the years, in part because of the vast number of products and parties regulated by FDA. For example, FDA's 1977 annual report estimates the overall number of food processing, manufacturing, and warehouse facilities regulated by the agency at 77,000, and FDA conducts approximately 19,000 food establishment inspections annually (Ref. 9). As a result of the vast industry that the agency must regulate, FDA ceased relying exclusively on case-by-case litigation in the late 1960's and adopted a combined policy of promulgating regulations, relying on self-regulation by the industry, and, within the limits of available resources, enforcing regulations when the industry fails to comply with them.

In 1967, based on its experience in regulating the food industry, FDA proposed regulations to establish CGMP criteria for the manufacturing, processing, packing, or holding of food, to bring about compliance with section 402(a)(4) of the act (see the **Federal Register** of December 15, 1967 (32 FR 17980)). Because comments resulted in significant changes in the proposal, the agency reproposed the regulations in the **Federal Register** of December 20, 1968 (33 FR 19023) and issued the final regulations in the **Federal Register** of April 26, 1969 (34 FR 6977). At the request of the General Accounting Office (GAO) in 1971, FDA inspected 97 food manufacturing plants of all types, which were selected at random from some 4,500 food manufacturing and processing plants located in 6 FDA districts. Insanitary conditions having the potential for or having already caused product adulteration were observed in many facilities. The results of the survey appear in the GAO report, "Dimensions of Insanitary Conditions in the Food Manufacturing Industry" (Ref. 11).

The agency initiated a series of actions to improve conditions in the food industry. In addition to its normal inspection programs, FDA held several meetings with representatives of various segments of the food industry to exchange ideas and gather information helpful for developing improved good manufacturing practices in the industry. Based on these discussions, FDA proposed CGMP regulations for cacao products and confectionaries (hereinafter referred to as the candy CGMP's) in the **Federal Register** of November 26, 1973 (38 FR 32554) and issued the final candy CGMP's in the **Federal Register** of June 4, 1975 (40 FR 24162); it also proposed analogous regulations for bakery foods in the **Federal Register** of February 12, 1976 (41 FR 6456) and tree nuts and peanuts in the **Federal Register** of June 30, 1976 (41 FR 27000). The agency selected these segments of the food industry as the first subjects of specific CGMP regulations due to the cooperation of the representatives of those segments. They also represent an approximate cross section of the food industry. The CGMP regulations for the specific segments of the food industry were proposed as merely complementary provisions to the CGMP regulations for the overall food

industry (21 CFR Part 110, the so-called umbrella CGMP's).

The agency's experience in regulating the food industry in general, including drafting CGMP proposals for other particular segments of the food industry and reviewing the comments on the outstanding CGMP proposals, has shown that problems to be addressed by those CGMP regulations are common throughout all segments of the food industry, e.g., personnel, plant construction, and sanitation. Accordingly, the agency believes that the most efficient way to proceed now is to revise the umbrella CGMP regulations rather than repetitively to propose identical regulations for numerous segments of the industry. Therefore, the agency is staying the rulemaking proceedings on the CGMP proposals for bakery foods and tree nuts and peanuts pending an evaluation of the comments on this proposal. After the comments are evaluated, the agency will determine what action to take with respect to the stayed rulemaking proceedings and will consider whether all or part of the candy CGMP's should continue in effect.

The CGMP regulations already in effect detail the practices to be followed to ensure (1) that food is manufactured, processed, packed, and held under conditions that are sanitary, and (2) that such food is safe, clean, and wholesome. In general, this notice proposes to revise and update the requirements for plant personnel; plant design and construction; sanitary operations, facilities, and controls; equipment and utensils; regulating and recording controls; processing operations; and coding and recordkeeping. Preliminary drafts of this proposal were reviewed by the Food Safety and Quality Service, United States Department of Agriculture, and the National Marine Fisheries Service, National Oceanographic and Atmospheric Administration, United States Department of Commerce. The agency has carefully considered the suggestions received from these two agencies and has incorporated them, where appropriate, into the proposal. Copies of the correspondence are on file with the Hearing Clerk, FDA (Refs. 12 and 13). The following is a section-by-section analysis of the proposal:

**Definitions**

Section 110.3 (21 CFR 110.3) includes definitions of new terms and revised definitions of previously used terms that have uniform applicability. To eliminate any possible misunderstanding, the agency is also revising the definitions to ensure that they are consistent with the other regulations in this subchapter. These definitions are based on the agency's experience in regulating foods, common usage in the regulated industry, and, in the case of new § 110.3 (l) and (p), the material in Refs. 14 and 15.

**Current Good Manufacturing Practices**

Section 110.5 (21 CFR 110.5) emphasizes that the CGMP regulations identify the applicable criteria for implementing the requirements of section 402(a) (3) and (4) of the act. Moreover, this section explains that foods covered by specific CGMP regulations in the subchapter are still subject to the requirements imposed by this part.

Under section 701(a) of the act (21 U.S.C. 371(a)), FDA has the authority to promulgate regulations for the efficient enforcement of the act, and such regulations have been held to have the force and effect of law. See *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F. 2d 688, 695–698 (2d Cir., 1975). The courts have also expressly held that FDA has the authority to promulgate substantive regulations defining current good manufacturing practices for the food industry *National Confectioners Ass'n* v. *Califano*, 569 F. 2d 690 (D.C. Cir., 1978). See *Nova Scotia Food Products Corp.* v. *U.S.*, 568 F. 2d 240, 245–248 (2d Cir., 1978). Furthermore, since the promulgation of the CGMP regulations in 1969, the Secretary of Health, Education, and Welfare has delegated authority to exercise the functions vested in the Secretary under section 361 of the Public Health Service Act (42 U.S.C. 264) to the Commissioner of Food and Drugs (see 35 FR 606 (January 16, 1970), corrected at 35 FR 3001 (February 13, 1970), codified at 21 CFR 5.1(a)(4)). Under this provision, the Commissioner is authorized to issue and enforce regulations for any measures that, in the Commissioner's judgment, are necessary to prevent the introduction, transmission, or spread of food-borne communicable diseases from one State to another. Because this authority is designed to eliminate the introduction of diseases such as typhus from one State to another, this authority must of necessity be exercised upon the disease-causing substance within the State where the food is manufactured, processed, or held. Due to the nationwide, interrelated structure of the food industry, communicable diseases may, without proper intrastate food controls, easily spread interstate, as the annual Center for Disease Control reports on food-borne Salmonellosis show (Refs. 16 and 17). The Commissioner therefore assumes authority to promulgate regulations under the Public Health Service Act to assure that foods are manufactured, processed, packed, or held under sanitary conditions so as to be safe, wholesome, and otherwise fit for food. Regulations promulgated under that statute also have the force and effect of law. See *State of Louisiana* v. *Mathews*, 427 F. Supp. 174 (D. La., 1977).

**Personnel**

Section 110.10 (21 CFR 110.10) summarizes the responsibilities imposed on the plant management to take reasonable measures and precautions to satisfy the articulated criteria for disease control, cleanliness, and education and training. These standards and criteria will help to prevent the spread of disease among the workers and from the workers to the food processing area and the food itself.

**Exclusions**

Section 110.19 (21 CFR 110.19) codifies FDA's historical exemption from the "umbrella" CGMP regulations of establishments that are engaged in the harvesting, storage, or distribution of one or more raw agricultural commodities that are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public. Subsequent handlers of the commodities would be subject to the CGMP regulations, and food from those commodities is thus brought into compliance with the act at the later stages of the manufacturing, processing, packing, or holding. The Commissioner, however, will issue special regulations when necessary to encompass any excluded operation.

**Plants and Grounds**

Section 110.20 (21 CFR 110.20) describes the general principles of plant design and construction that are necessary to protect food from insanitary conditions and unwholesomeness and also to prevent the spread of disease-causing microorganisms through food. The proposal includes a new subparagraph to explain ways to reduce the possibility of microorganism, chemical, filth, or other contamination of end products, raw materials, and packaging materials. It recommends separating each step in the operation, from receiving the raw materials, to packing and shipping the end product, to cleaning, sanitizing, and maintaining the operations. Several mechanisms of separating the operations are set out in the regulation: location, partition, air flow, enclosed systems, or any other effective means

that will separate the systems and prevent their contamination.

These requirements were adopted in the candy CGMP's, and FDA has found them useful in that area. Comments received in response to the candy CGMP proposal and proposals for bakery foods and tree nuts and peanuts CGMP regulations, which also included these provisions, interpreted them as requiring the affected parties to separate each step in their operations by partitions. The agency advises that the use of partitions is only one method of separating operations, and that other means are acceptable. However, the operations should be separated so as to ensure that no contamination occurs. Additionally, the new subparagraph recommends that the design of the plant permit management to take precautions to protect products in out-door bulk fermentation vessels from insanitary conditions.

**Sanitary Operations**

Section 110.35 (21 CFR 110.35) sets out the basic rules for sanitation and cleanliness of buildings, fixtures, and other physical facilities, equipment, and utensils. The rules describe the requirements for general maintenance, control of animals and vermin, sanitation of equipment and utensils, and storage and handling of cleaned equipment and utensils. This section has been expanded to emphasize and describe proper use of cleaning compounds, sanitizing agents, and pesticide chemicals to protect raw material, packaging material, and finished food from contamination.

**Sanitary Facilities and Controls**

Section 110.37 (21 CFR 110.37) lists and describes the minimally acceptable adequate sanitary facilities and accommodations for all the food-handling operations. These include, but are not limited to, water supply, plumbing, sewage disposal, toilet facilities, hand-washing facilities, and rubbish and offal disposal.

A new subparagraph added to paragraph (b) prohibits backflow or cross connection between piping systems that carry water for food processing use and piping systems that discharge waste water or sewage. This prohibition is necessary to prevent spread of filth or disease-causing microorganisms through the sanitation facilities. In addition, paragraph (e) is revised to describe better the requirements for hand-washing facilities and has adopted the paragraph used in the candy CGMP's, which the agency believes is applicable for all food handling operations.

**Equipment and Utensils**

Section 110.40 (21 CFR 110.40) describes the general rules for cleanliness and maintenance of equipment and utensils, which must be designed and constructed so that they can be cleaned and maintained to prevent adulteration of the food. To prevent problems that can arise in this area, the agency had added the following requirements:

(a) Food-contact surfaces must be corrosion free when in contact with food.

(b) Seams in food-contact surfaces must be smoothly bonded or maintained to minimize the accumulation of food particles. Surfaces such as stainless steel are not required; other surface materials also can be maintained to prevent microbial contamination.

(c) Surfaces of equipment that do not come in contact with food are to be constructed so that they can be kept clean by maintenance in accordance with the other provisions of the regulations.

(d) Systems that hold, convey, and process ingredients and products must be designed and constructed so that they also can be kept clean.

(e) Temperature-controlling, -re - cording, and -measuring devices on equipment used to control and prevent the growth of microorganisms must be accurate and effective for their designated use. Because killing the microorganisms is critical, the devices must ensure that the food is adequately processed.

(f) Freezer and cold storage compartments used for holding materials capable of supporting the growth of microorganisms must be fitted with suitable temperature-indicating or -recording devices.

(g) Instruments used for measuring or regulating conditions that control or prevent undesirable microbial growth in foods must be properly maintained (e.g., compressed air introduced into foods must be clean). Food-contact surfaces and gases, in addition to compressed air, must comply with the requirements of section 409 of the act (21 U.S.C. 348). Any pesticides used must be used in accordance with section 408 of the act (21 U.S.C. 346a) and the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135 note).

(h) Although most former industrial uses of polychlorinated biphenyls (PCB's) have been curtailed, if not eliminated, the agency believes that it is necessary to retain a restricted uses paragraph for PCB's in the proposed regulation for the following reasons: PCB's represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment and to contaminate certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Because PCB's are toxic chemcials, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in food plants.

**Processes and Controls**

Section 110.80 (21 CFR 110.80) adds a quality control operation to ensure that all operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and storing of food are conducted in accordance with adequate sanitation principles. This program requirement is based on FDA's experience in conducting approximately 19,000 food establishment inspections annually. Most operations have control procedures of this nature, and quality control procedures of this type help to ensure that raw materials and finished products are fit for food, that packaging materials are safe and suitable, and that all are in compliance with the act.

The agency is also proposing to amend the paragraph on raw materials to establish new subparagraphs addressing the issue of the fitness of raw materials. These materials must comply with the act. They must be held under proper storage conditions, and they must not contain microorganisms that can produce food poisoning or other disease in humans, or they must be properly treated to destroy such microorganisms.

The agency has reexamined the requirement in the candy CGMP's (21 CFR 118.80(b)(1), and (4)(i), and (c)(1)) that such foods be held at temperatures below 40°F (4.4°C). As the refrigeration temperature rises, the shelf life of foods is generally shortened. Although some pathogenic bacteria can reproduce at temperatures between 40°F (4.4°C) and 45°F (7.2°C), growth is slow (Refs. 18 through 26). The agency has reviewed the added risk of allowing a maximum storage temperature of such foods of 45°F (7.2°C) rather than 40°F (4.4°C) and concludes that this risk is minimal.

On the other hand, the agency believes the added expenditure of energy and cost of maintaining foods at 40°F (4.4°C) versus 45°F (7.2°C) is significant. A refrigerator operating at an ambient air temperature of 70°F (21.1°C) requires 20 percent more energy to operate at a temperature of 40°F (4.4°C) than to operate at a temperature of 45°F (7.2°C) (Refs. 27 and 28). Therefore, the agency is proposing to require that materials capable of supporting rapid microbial growth be stored at a temperature of 45°F (7.2°C) or below.

The agency is also expanding paragraphs concerning processing operations by proposing to require that: (a) foods that can support the rapid growth of microorganisms be held so that the risk of such growth is minimized; (b) measures taken to destroy or prevent the growth of microorganisms of public health significance be adequate under the conditions of manufacture; (c) raw materials, work-in-process, rework, finished foods, and refuse be handled so that the risk of having a contaminated food is minimized; (d) measures be taken to prevent the inclusion of extraneous material in finished products; (e) adulterated materials be properly disposed of or, if it is feasible, be reconditioned; (f) mechanical processing be performed so as not to contaminate raw materials, ingredients, or finished products; (g) batters, breadings, sauces, and other preparations be treated or maintained so that they are free of contamination; (h) the filling, assembling, and packaging of food be performed so as not to contaminate the finished food products; (i) foods relying on low water activity for preventing the growth of most microorganisms be processed to, and maintained at, a safe moisture level; and (j) foods relying on low pH for preventing the growth of microorganisms of public health significance be maintained at a pH of 4.6 or below.

**Coding**

To emphasize the importance of this provision, new § 110.91 (21 CFR 110.91) deals expressly with product coding. In § 110.80(i) of the current umbrella GMP regulations, which this proposal would supersede, the agency suggests that meaningful coding of products should be used to enable positive lot identification. Positive lot identification facilitates, identification and segregation of contaminated products or products that may be otherwise unfit for their intended use. The current regulations also recommend that records be retained for a period that exceeds the shelf life of the product, but for no more than 2 years.

In the past decade, voluntary product recalls by manufacturers have become one of FDA's most useful regulatory tools, and the agency has promulgated guidelines describing the policies and procedures that FDA follows and guidelines that firms should follow in the conduct of product recalls (see the Federal Register of June 16, 1978 (43 FR 26202)). In fiscal year 1975 there were 133 recalls of food products, including misbranding violations, and 163 in fiscal year 1976 (Ref. 9). These experiences have shown that product coding is an essential element of this regulatory tool. Congress has recognized the utility of product coding, as have many members of the food industry, who have developed guidelines for their segments of the industry (Ref. 34). Furthermore, the United States Court of Appeals for the District of Columbia Circuit recognized the self-evident rationality of this procedure in its opinion upholding the coding provision in the candy CGMP's. See *National Confectioners Ass'n* v. *Califano*, 569 F.2d 690, 695 (D.C. Cir., 1976).

Many companies are already coding products (Ref. 34), and, based upon coding's recognized utility and accepted use in many segments of the food industry, the agency believes product coding should be mandatory for all foods. Accordingly, the agency is proposing, except where specifically exempt, to require permanently legible marks at a readily visible location on each finished food package delivered or displayed to purchasers (except for over-the-counter retail sales at the site of manufacture), so that the code marks can be easily seen on the unopened package. The marks must identify at least the plant where the product was packed and the product lot or packaging lot. It is recognized that a packaging lot may contain food manufacturerd on more than 1 day but packaged on a single day.

The agency is proposing to exempt the following products from the requirement that code marks be placed on each finished food package: (a) individually wrapped confectionery, each piece weighing ½ ounce or less, subject to § 1.24(a)(4); (b) food received in bulk containers at a retail establishment, and subject to § 101.100(a)(2), and (c) food repackaged at a retail establishment subject to § 101.100(b) provided that the package in which the food item is shipped to the retailer shall bear a code mark. The agency is willing to consider other similar exemptions if they are considered necessary and if such exemptions will allow the easy recall of food items from the retailers, institutions, manufacturers, or repackers to whom the products are shipped.

This proposed coding requirement is somewhat more stringent than the coding provision in the candy CGMP's in that it does not, as a general rule, give the manufacturer the option of placing the code mark on the shipping container rather than on the individual finished food package. The agency believes, however, that the proposed requirement is consistent with the coding practices now used by much of the food industry and that it will facilitate identification of recalled products.

**Warehousing and Distribution**

Revised § 110.93 (21 CFR 110.93) describes and establishes the requirement that storage and transportation of finished foods be conducted under conditions that will prevent physical, chemical, and microbiological contamination.

**Records**

Section 110.100 (21 CFR 110.100) lists current recordkeeping requirements, amended to conform to those promulgated and upheld in the candy GGMP's. These recordkeeping requirements are correlated with the other CGMP requirements and require the affected parties to maintain (a) records on the results of examinations or copies of supplier guarantees or certifications verifying that the raw materials comply with the basic act and other FDA regulations under proposed § 110.80(a); (b) records of processes that are specified in proposed § 110.80(b) and are intended to destroy or prevent the growth of microorganisms of public health significance in the foods; and (c) distribution records that identify initial distribution of finished food under proposed § 110.93 to facilitate recalls. The agency proposes that these records

be kept for 2 years or for the shelf life of the product, whichever is shorter.

### Natural or Unavoidable Defects

Section 110.110 (21 CFR 110.110) alerts all affected parties that current action levels for natural or unavoidable defects in food for human use that present no human health hazard are publicly available. Because the action levels for these defects are subject to revision, it is impractical to include them in the regulation, but they are available from FDA on request, and the regulation identifie show this information can be obtained.

For editorial consistency, the agency also proposes to revise § 20.100(c)(8) (21 CFR 20.100(c)(8)) to reflect a cross reference to proposed § 110.110(e), which contains cross-referenced action level provisions now located in § 110.99(e) (21 CFR 110.99(e)).

The agency plans to hold public hearings for the purpose of receiving information and views regarding the issues raised by this proposal and the impact the proposed regulations will have on the food industry, especially small businesses. The hearings will be held in Chicago, IL, on September 11, 1979; San Francisco, CA, on October 3, 1979; and Atlanta, GA, on October 24, 1979. Representatives of small businesses will be encouraged to participate. Specific information about these hearings will be published in the **Federal Register** on or about June 15, 1979.

The agency proposes that the final regulations based on this proposal be effective 180 days after the date of publication of the final regulations in the **Federal Register.**

The agency has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

### References and Material Consulted

1. Memo on Legislative History of section 404 (21 U.S.C. 344) of the Federal Food, Drug, and Cosmetic Act.

2. S. Rep. No. 493, 73d Cong., 2d Sess. (1934).

3. S. Rep. No. 361, 74th Cong., 1st Sess. (1935).

4. S. Rep. No. 646, 74th Cong., 1st Sess. (1935).

5. H.R. Rep. No. 2755, 74th Cong., 2d Sess. (1936).

6. S. Rep. No. 152, 75th Cong., 1st Sess. (1937).

7. S. Rep. No. 91, 75th Cong., 1st Sess. (1937).

8. H.R. Rep. No. 2139, 75th Cong., 3d Sess. (1937).

9. 1977 Food and Drug Administration Annual Report.

10. Memoranda summarizing FDA's food regulatory actions since 1950.

11. General Accounting Office Report, "Dimensions of Insanitary Conditions in the Food Manufacturing Industry."

12. Letter dated November 4, 1977, from Dr. Robert Angelotti, Administrator, Food Safety and Quality Service, USDA, to Dr. Howard R. Roberts, Acting Director, Bureau of Foods, FDA, containing FSQS comments on preliminary draft of GMP proposal and FDA reply dated May 31, 1979.

13. Letter dated November 8, 1977, from Joseph W. Slavin, Assistant Director for Fisheries Development, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Dept. of Commerce, to Dr. Howard R. Roberts, Acting Director, Bureau of Foods, FDA, containing NMFS comments on preliminary draft of GMP proposal and FDA reply dated May 31, 1979.

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15. Stoloff, L., "Calibration of Water Activity Measuring Instruments and Devices: Collaborative Study," *Journal of the Association of Official Analytical Chemists*, 61:1166, 1978.

16. Center for Disease Control: Salmonella Annual Summaries 1975 (September 1976).

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19. Michener, H. D. and R. P. Elliott, "Minimum Growth Temperatures for Food Poisoning, Fecal Indicator, and Psychrophilic Microorganisms," *Advances in Food Research*, Edited by Chichester, C. O., 13:349, 1964.

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21. Tanner, F. W., P. R. Beamer, and C. I. Rickher, "Further Studies on Development of *Clostridium botulinum* in Refrigerated Foods," *Food Research*, 5:323, 1940.

22. Kelly, F. G. and G. M. Dack, "Experimental Staphylococcal Food Poisoning. A Study of the Growth of a Food-Poisoning Staphylococcus and the Production of an Enterotoxic Substance in Bread and Meat," *American Journal of Public Health*, 26:1077, 1936.

23. Miller, W. A. and M. L. Smull, "Efficiency of Cooling Practices in Preventing Growth of Micrococci," *Journal of the American Dietetic Association*, 31:469–473, 1955.

24. Longree, K. and J. C. White, "Cooling Rates and Bacterial Growth in Food Prepared and Stored in Quantity I. Broth and White Sauce," *Journal of the American Dietetic Association*, 31:124–132, 1955.

25. Wiedeman, K., M. A. Watson, J. Neill, and W. G. Walter, "Effect of Holding time on Bacteria in Chicken Casserole," *Journal of the American Dietetic Association*, 33:37–41, 1957.

26. Weideman, K., M. A. Watson, H. L. Mayfield, and W. C. Walter, "Effect of Delayed Cooking on Bacteria in Meat Loaf," *Journal of the American Dietetic Association*," 32:935–940, 1956.

27. American Society of Heating, Refrigerating and Air Conditioning Engineers, 1963, "ASHRAE Guide and Data Book, Fundamentals and Equipment," Published by ASHRAE, New York, NY, p. 782.

28. Private communication from R. W. Dickerson, Jr., January 4, 1978.

29. Food Services Sanitation Manual including A Model Food Service Sanitation Ordinance (1940, 1943, 1962; revision published, 1976).

30. Draft Retail Food Store Sanitation Ordinance (1978).

31. The Vending of Food and Beverages including A Model Sanitation Ordinance (1965, revised 1978).

32. Grade A Pasteurized Milk Ordinance . 1965 Recommendation of the United States Public Health Service (being revised, 1979).

33. Grading and Inspection, General Specifications for Approved Plants and Standards for Grades of Dairy Products (7 CFR Part 58).

34. Proposed Amendments to the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act to authorize a Uniform System of Coding for Packaged Food: Hearings on S. 3012—Amendment No. 1838, Before the Subcommittee for Consumers of the Senate Committee on Commerce, 93d Cong., 2d Sess. (1974).

Copies of the items listed above, except for items 2 through 8, are on file with the Hearing Clerk, FDA.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 302, 303, 304, 402(a), 701(a), 52 Stat. 1043–1046 as amended, 1055 (21 U.S.C. 332, 333, 334, 342(a), 371(a))), and the Public Health Service Act (sec. 361, 58 Stat. 703 (42 U.S.C. 264), and the authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

1. In Part 20, § 20.100 is amended by revising paragraph (c)(8) to read as follows:

**§ 20.100 Applicability; cross-reference to other regulations.**

* * * * *

(c) * * *

(8) Action levels for natural and unavoidable defects in food for human use, in § 110.110(e) of this chapter.

* * * * *

2. By revising Part 110 to read as follows:

## PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING HUMAN FOOD

### Subpart A—General Provisions

Sec.
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Authority: Secs. 302, 303, 304, 402(a), 701(a), 52 Stat. 1043–1046 as amended, 1055 (21 U.S.C. 332, 333, 334, 342(a), 371(a)); sec. 361, 58 Stat. 703 (42 U.S.C. 264)).

### Subpart A—General Provisions

#### § 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions shall also apply:

(a) "Acid foods or acidified foods" means foods that have an equilibrium pH of 4.6 or below.

(b) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) "Batter" means a semifluid substance, usually composed of flour and other ingredients, in which principal components of food are dipped or with which they are coated.

(d) "Blanching" means a hot water or steam direct-scalding treatment of foodstuffs for a sufficient time and at a sufficient temperature to inactivate the naturally occurring enzymes.

(e) "Corrosion-free" as it applies to food-contact surfaces means that the surface material is free of corrosion that may cause contamination of the food.

(f) "Critical control point" means a point in a food process where lack of control may cause, allow, or contribute to adulteration of the final product or any raw materials used therein.

(g) "Food-contact surfaces" are those surface that contact food and those surfaces from which drainage onto foods or onto surfaces that contact food ordinarily occurs during the normal course of operations.

(h) "Lot" means a collection of primary containers or units of the same size, type, and style containing a finished product produced under conditions as nearly uniform as possible and designated by a common container code or marking; and, in any event, "lot" means no more than a day's production.

(i) "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, processing, packaging, labeling, or holding of human food.

(j) "Quality control operation" means a planned and systematic procedure for all actions necessary to ensure that the food is free from adulteration.

(k) "Rework" means clean, unadulterated product, removed from processing, that is suitable for reprocessing and for use as food.

(l) "Safe-moisture level" is a level of moisture low enough to prevent the growth of microorganisms in the finished product. The maximum safe moisture level for a food is based on its water activity ($a_w$). An $a_w$ will be considered safe for a food if adequate data are provided that demonstrate that the food at or below the given $a_w$ will not support the growth of microorganisms.

(m) "Sanitize" means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing numbers of other microorganisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

(n) "Shall" is used to state mandatory requirements.

(o) "Should" is used to state recommended or advisory procedures or to identity recommended equipment.

(p) "Water activity" ($a_w$) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

#### § 110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (l) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit as food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(b) Foods covered by specific current good manufacturing practice regulations also are subject to the requirements of those regulations. Compliance with the criteria and definitions in this part is necessary for the prevention and control of communicable diseases under section 361 of the Public Health Service Act (42 U.S.C. 264).

#### § 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* No person, while affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by that person, or of disease being transmitted by that person to other individuals.

(b) *Cleanliness.* All persons, while working in direct contact with food preparation, food ingredients, or food-contact surfaces shall conform to hygients practices while those persons are on duty, to the extent necessary to prevent contamination of food products. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing proper outer garments in a manner that prevents the contamination of food.

(2) Maintaining a high degree of personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to prevent contamination by undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all insecure jewelry and, during periods in which food is manipulated by hand, removing from hands any jewelry that cannot be adequately sanitized.

(5) If gloves are used in food handling, maintaining them in an intact, clean, and sanitary condition. The gloves should be of an impermeable material

except where their usage would be inappropriate or incompatible with the work involved.

(6) Wearing hair nets, headbands, caps, beard covers, or other effective hair restraints in an effective manner.

(7) Not storing clothing or other personal belongings in areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.

(8) Not eating food, drinking beverages, or using tobacco in areas where food or food ingredients are exposed or in areas for washing equipment or utensils.

(9) Taking any other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be cognizant of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

**§ 110.19 Exclusions.**

The following operations are excluded from coverage under these general regulations. The Commissioner, however, will issue special regulations when necessary to cover these excluded operations: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

## Subpart B—Buildings and Facilities

**110.20 Plant and grounds.**

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will not cause food to be contaminated. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, or other pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food products by seepage, by foot-borne filth, or by providing a breeding place for rodents, insects, or other pests.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in subparagraphs (1) through (3) of this paragraph, care shall be exercised in the plant by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-processing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations and production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of end products, raw materials, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by any effective means including the separation, by location, partition, air flow, enclosed systems, or other effective means, of the following operations:

(i) Receiving.

(ii) Raw material storage.

(iii) Food preparation and processing operations.

(iv) Weighing, wrapping, packaging, and packing.

(v) Finished product storage and shipping.

(vi) Portable equipment and utensil cleaning and sanitizing.

(vii) Equipment and vehicle maintenance.

(3) Permit the taking of proper precautions to protect products in outdoor bulk fermentation vessels. This may be accomplished by an effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for birds and rodents.

(iii) Checking on a regular basis for insect infestation.

(iv) Skimming the fermentation vessels frequently.

(4) Provide floors, walls, and ceilings that are of such construction as to be adequately cleanable and that shall be kept clean and in good repair. Fixtures, ducts, and pipes shall be installed in such a manner that drip or condensate does not contaminate foods, raw materials, or food-contact surfaces. Aisles or working spaces between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting to hand-washing areas, dressing and locker rooms, and toilet rooms and to all areas where food or food ingredients are examined, processed, or stored and where equipment and utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and noxious fumes or vapors (including steam) in areas where they may contaminate food. Fans and other air-blowing equipment shall be located and operated in a manner that does not cause contamination of raw materials, work-in-process, rework, finished foods, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, effective screening or other protection against birds, animals, and vermin (including, but not limited to, insects and rodents).

**§ 110.35 Sanitary operations.**

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning and sanitizing of utensils and equipment shall be carried out in a manner that prevents contamination of raw material, food-packaging material, or finished food. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only those toxic materials that are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or

processing operations shall be used or stored in the plant. Poisonous or dangerous cleaning compounds, sanitizing agents, and pesticide chemicals shall be applied, stored, and held in a manner that prevents food or food-packaging material contamination. These materials shall be identified and used only in a manner and under conditions that will be safe for their intended use. All applicable regulations promulgated by the Environmental Protection Agency for the application, use, or holding of these materials shall be followed.

(b) *Animal and vermin control.* No animals or birds, other than those essential as raw materials, shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under precautions and restrictions that will prevent the contamination of food and food-packaging materials with illegal residues.

(c) *Sanitation of equipment and utensils.* All utensils and food-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products.

(1) Food-contact surfaces of equipment used for processing or holding low-moisture raw materials or foods shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall be sanitized when necessary and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to prevent the introduction of undersirable microorganisms into food products, all utensils and food-contact surfaces of equipment used in the plant shall be cleaned and sanitized before use and after any interruption during which the utensils and contact surfaces may have become contaminated. Where the equipment and utensils are used in a continuous production operation, the contact surfaces of the equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles, and other debris.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that prevents contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, machine, or device is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.

(d) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment and utensils with food-contact surfaces should be stored in a location and manner that protects food-contact surfaces from splash, dust, and other contamination.

**§ 110.37 Sanitary facilities and controls.**

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts foods or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where required for the processing of food, the cleaning of equipment, utensils, or containers, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Neither constitute a source of contamination to foods, food products or ingredients, water supplies, equipment or utensils nor create an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Ensure that there is not backflow from, or crossconnection between, piping systems that carry water for food or food-processing use and piping systems that discharge waste water or sewage.

(c) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate toilet and associated hand-washing facilities within the plant. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is exposed to airborne contamination, except where alternate means have been taken to prevent such contamination (such as double doors, positive air-flow systems, etc.).

(e) *Hand-washing facilities.* Adequate and readily accessible hand-washing and, if necessary, sanitizing facilities shall be provided in the plant for employees who may handle unprotected food, unprotected packaging materials, and food-contact surfaces. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand-cleaning and sanitizing preparations, sanitary towel service or suitable drying services, and, if necessary, sanitizing preparations. These facilities should be equipped with water control valves so designed and constructed as to prevent recontamination of clean, sanitized hands. Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated, shall be conspicuously posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces. Where appropriate, such signs shall also direct employees to sanitize their hands. Refuse receptacles that are constructed and maintained in a manner that precludes contamination of the products shall be used where appropriate.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces, and water supplies.

## Subpart C—Equipment

### § 110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion free when in contact with food. They shall be made of nontoxic material that will withstand the environment of its intended use and the action of food ingredients, cleaning compounds, and sanitizing agents. All food-contact surfaces shall be maintained to prevent product contamination and shall be in compliance with section 409 of the act.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles or to prevent microbiological contamination in places where dirt or organic material might accumulate.

(c) Equipment that is in the processing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Ingredient and product-holding, conveying, and processing systems that include, but are not limited to, gravimetric, pneumatic, closed, and automated systems shall be of a design and construction that enables them to be cleaned.

(e) Regulating and recording controls, thermometers, other temperature-measuring devices, and temperature-recording devices on equipment used to sterilize, pasteurize, or otherwise control or prevent growth of microorganisms in raw materials or products shall be accurate, effective, and adequate in number for their designated uses.

(f) Each freezer and cold storage compartment used for storing and holding raw materials or products capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(g) Instruments used for measuring or regulating pH, acidity, water activity, or other conditions that control or prevent undesirable microbial growth in foods shall be precise and properly maintained.

(h) All compressed air or other gases mechanically introduced into foods or used to clean food-contact surfaces or equipment shall be properly filtered or washed, shall be free of oil and other extraneous material that might contaminate the foods, and shall be in compliance with section 409 of the act.

(i) Restrictions on the industrial uses of polychlorinated biphenyls (PCB's) provided in § 109.15 of this chapter shall also be applicable to the industrial uses of PCB's in the production, handling, and storage of food. Equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's, except for electrical transformers and condensers containing PCB's in sealed containers.

## Subpart D [Reserved]

## Subpart E—Production and Process Controls

### § 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that raw materials and finished products are fit for food, that food-packaging materials are safe and suitable, and that all of the foregoing materials are in compliance with the Federal Food, Drug, and Cosmetic Act. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination such as filth, harmful chemicals, undesirable microorganisms, or any other objectionable material to the processed food. Chemical, microbiological, or extraneous-material testing procedures shall be utilized where necessary to identify sanitation failures or food contamination, and all foods and ingredients that have become contaminated shall be rejected or treated or processed to eliminate the contamination.

(a) *Raw materials and ingredients.* [1] Raw materials and ingredients shall be inspected and segregated as necessary to ensure that they are clean and fit for processing into human food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as required to remove soil or other contamination. Water used for washing, rinsing, or conveying of food products shall be of adequate quality, and water shall not be reused for washing, rinsing, or conveying products in a manner that may result in contamination of food products. Containers and carriers of raw ingredients should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of the products.

(2) Raw materials and ingredients shall not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during processing operations to destroy such microorganisms.

(3) Raw materials susceptible to contamination with aflatoxin or other natural toxins shall be examined, sorted, or treated to ensure that the finished foods comply with current Food and Drug Administration requirements, guidelines, and action levels for poisonous or deleterious subtances before these materials are incorporated into finished products. Compliance with this requirement may be accomplished by purchasing these materials under a supplier's guarantee or certification, or may be verified by analyzing these materials for aflatoxins and other natural toxins.

(4) Raw materials and rework susceptible to contamination or infestation by animals, birds, vermin, microorganisms, or extraneous material shall comply with current Food and Drug Administration regulations, guidelines, and action levels for natural or unavoidable defects before these materials are incorporated into finished products. Compliance with this requirement may be verified by any effective means, including examination of these materials for infestation and contamination.

(5) Raw materials shall be held in containers so designed and constructed as to prevent their contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent their adulteration.

(6) Frozen raw materials shall be kept frozen exept for the period of time actually required for processing and shall be defrosted in a manner that does not adversely affect their use as food.

(7) Liquid or dry ingredients received and stored in bulk form shall be held in a manner that prevents any direct or indirect contamination.

(b) *Processing operations.* (1) Processing equipment and utensils and finished product containers shall be maintained in a sanitary condition through frequent cleaning with appropriate cleaning agents, and by sanitization where indicated. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food processing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for undesirable bacterial or other microbiological growth, toxin formation, or deterioration or contamination of the processed product or ingredients. Compliance with this requirement may require careful monitoring of such physical factors as time, temperature, humidity, $a_w$, pH, pressure, flow rate, and such processing operations as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of the processed products.

(3) Foods that can support the rapid growth of microorganisms of public health significance or that are subject to decomposition as a result of microbial multiplication shall be held in a manner that minimizes the growth of those microorganisms. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45° F (7.2° C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods at 0° F (−17.8° C) or below.

(iii) Maintaining hot foods at 140° F (60° C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, pasteurizing, freezing, refrigerating, controlling pH or controlling $a_w$ that are taken to destroy or prevent the growth of microorganisms of public health significance shall be adequate under the conditions of manufacture for a given food to ensure destruction or the prevention of growth of those microorganisms.

(5) Rework shall be held in properly identified containers, shall be handled and stored as raw material, and shall meet raw material requirements before reprocessing.

(6) Work-in-process shall be handled in a manner that prevents its contamination.

(7) Effective measures shall be taken to prevent cross contamination between raw materials and finished foods, or between refuse and these materials. When any of these materials are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in a contaminated product. Materials and products transported by conveyor shall be protected against contamination from extraneous material.

(8) Equipment, containers, and utensils used to convey, process, hold, or store raw materials, work-in-process, rework, or finished foods shall be constructed, handled, and maintained during processing or storage in a manner that prevents the contamination of raw materials, rework, or finished foods.

(9) Effective measures shall be taken to prevent the inclusion of metal or other extraneous material in the finished foods. Compliance with this requirement may be accomplished by using sieves, magnets, electronic metal detectors, or other suitable effective means.

(10) Adulterated materials shall be disposed of in a manner that prevents the contamination of raw materials, rework, or finished foods. If the adulterated product is reconditioned, it shall be reexamined and found to be free from adulteration before being incorporated into finished foods.

(11) Mechanical processing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as not to contaminate raw materials, ingredients, or finished foods. Compliance with this requirement may be accomplished by providing adequate physical protection of raw materials, ingredients, and food products from contaminants that may drip, drain, or be drawn into the food product, by adequate cleaning and sanitizing of all food-contact surfaces and by using time and temperature controls at and between each step in the process.

(12) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(13) Batters, breading, sauces, gravies, dressings, and other preparations shall be treated or maintained in such a manner that they are free of contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during processing.

(vi) Disposing of batters at the end of each working day, or more frequently if required, to prevent significant microbial multiplication.

(14) Filling, assembling, and packaging and other operations shall be performed so as not to contaminate the finished food product. Compliance with this requirement may by accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points within the food process are identified and controlled.

(ii) Adequate cleaning and sanitizing of all food-contract surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in § 130.3(d) of this chapter.

(iv) Providing physical protection from airborne contamination.

(v) Requiring the use of sanitary handling procedures by employees.

(15) Foods such as, but not limited to, dry mixes, nuts, intermediate moisture foods, and dehydrated foods, that rely on the control of $a_w$ for preventing the growth of of microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the $a_w$ of ingredients and finished products.

(ii) Controlling the soluble solids-water ratio in finished products.

(iii) Protecting finished foods from moisture pickup, by use of a moisture barrier or by other means, so that the $a_w$ of the product does not increase to an unsafe level.

(16) Food such as, but not limited to, acid and acidified foods, that rely on the control of pH for preventing the growth of microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw foods, ingredients, and finished products.

(ii) Controlling the amount of acid or acidified foods added to low-acid ingredients.

(17) When ice is used in contact with food products, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with adequate standards and stored, transported, and handled in a sanitary manner.

(18) Food-processing areas and equipment used for processing human food should not be used to process nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

**§ 110.91 Coding.**

Permanently legible code marks shall be placed at a readily visible location on each finished food package delivered or displayed to purchasers so that the code marks can be readily seen on the unopened package. The marks shall identify at least the plant where the food was packed and the lot or packaging lot. This requirement does not apply to over-the-counter retail sales at the site of manufacture. The following foods are exempt from the requirement that coding marks be placed on each finished food package provided that the bulk containers received by the retail establishment contain code marks complying with this section:

(a) Individually wrapped pieces of "penny candy" and other confectionery entitled to exemption under § 1.24(a)(4) of this chapter.

(b) Foods entitled to exemption under § 101.100(a)(2) of this chapter.

(c) Foods entitled to exemption under § 101.100(b) of this chapter.

**§ 110.93 Warehousing and distribution.**

Storage and transportation of finished foods shall be under conditions that will prevent physical, chemical, and microbial contamination and will protect against undesirable deterioration of the food and the container. This deterioration includes, but is not limited to, contamination from insects, rodents and other vermin, toxic chemicals, pesticides, and the development of microorganisms of public health significance.

## Subpart F—Records and Reports

**§ 110.100 Records.**

(a) Records of results of examinations and/or copies of suppliers' guarantees or certifications that verify compliance with Food and Drug Administration regulations, guidelines, or action levels of raw materials, food-packaging materials, and finished foods, shall be maintained.

(b) Processing and production records of processes intended to pasteurize or otherwise treat materials to destroy, prevent, or control the growth of microorganisms of public health significance shall be maintained, and shall contain sufficient information to permit a public health evaluation of the processed food.

(c) Distribution records shall be maintained to identify the initial distribution, except for over-the-counter retail sales at the site of manufacture, of the finished food to facilitate, when necessary, the segregation and recall of specific lots that may have become contaminated or otherwise unfit for their intended use.

(d) The records required by paragraphs (a), (b), and (c) of this section shall be retained for a period of time that exceeds the shelf life of the finished product, except that they need not be retained for more than 2 years from the date of manufacture.

## Subpart G—Defect Action Levels

**§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard.**

(a) Some foods, even when produced under current good manufacturing and/or processing practices, contain natural or unavoidable defects at lower levels that are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under good manufacturing and processing practices and uses these levels for recommending regulatory actions.

(b) Defect action levels are established for products whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this part that food manufacturers shall observe current good manufacturing practices. Evidence obtained through factory inspection indicating such a violation renders the food unlawful, even though the amounts of natural or unavoidable defects are lower than the currently established action levels. The manufacturer of food shall at all times utilize quality control operations that will reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food unlawful, regardless of the defect level of the final food.

(e) A compilation of the current action levels for natural and unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), Rm. 5425, 200 C St. SW., Washington, DC 20204.

Interested persons may, on or before December 31, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four Copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executeive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is a on file with the Hearing Clerk, Food and Drug Administration.

Dated: May 29, 1979.

**Sherwin Gardner,**

*Acting Commissioner of Food and Drugs.*

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